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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 09/954,953   | 09/18/2001  | Giorgio Minotti      | LD0226(NP)              | 8528             |
| 7590   | 04/16/2004  |                      | EXAMINER                |                  |
| Marla J. Mathias<br>Bristol-Myers Squibb Company<br>Patent Department<br>P.O. Box 4000<br>Princeton, NJ 08543-4000 |             |                      | KHARE, DEVESH           |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 1623                    |                  |
|  |             |                      | DATE MAILED: 04/16/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/954,953             | MINOTTI ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Devesh Khare           | 1623                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 12 November 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 15-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 15-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_ .

Applicant's remarks filed on 11/12/03 is acknowledged.

Claims 1-14 have been cancelled. Claims 15-17 are currently pending in this application.

The Examiner's indication of allowable subject matter of claims 15-17 in the office action dated 9/15/2003, is vacated because during the course of reconsideration of the application, a prior art reference not previously disclosed by the applicants or the examiner came to light (see rejection below).

***35 U.S.C. 103(a) rejection***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

***Claims 15 and 16*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissery, U.S. Patent 5,908,835 in view of Loshak (XP-002222026: DG Dispatch-ECCO, Sept. 17, 1999).

Claim 15 is drawn to a chemotherapeutic combination comprising 4-desacetyl-4-methylcarbonate taxol and doxorubicin. Claim 16 which depends from claim 15 requires the combination of claim 15 to be in a pharmaceutically acceptable carrier.

Bissery teaches the antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic (see abstract). Bissery discloses taxol derivatives and an anthracycline antibiotic combination as the active agents for treating breast, ovarian and lung cancers (see col. 4, lines 46-51). Bissery also discloses the pharmaceutical acceptable carriers such as natural vegetable oils or liquid petroleum or

organic esters (col. 4, lines 21-24). The applicant's use of 4-desacetyl-4-methylcarbonate taxol is rendered obvious because the taxol, taxotere and their analogues and 4-desacetyl-4-methylcarbonate taxol have the same core structures (see applicant's figures 2 A, B and C) and the skilled artisan would expect these compounds to have similar properties to the compounds in the prior art. Bissery differs from the applicant's invention in that Bissery does not provide an explicit example of 4-desacetyl-4-methylcarbonate taxol and doxorubicin, however Bissery does provide motivation to use an antibiotic in combination with a taxol derivative to treat cancer.

Loshak teaches the treatment of breast cancer in women with a combination therapy using taxol with doxorubicin (first para.).

Therefore, one of ordinary skill in this art would have found applicant's chemotherapeutic combination comprising 4-desacetyl-4-methylcarbonate taxol and doxorubicin to have been obvious at the time the invention was made having the above references before him because Bissery teaches the antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic. Loshak teaches the use of doxorubicin in combination with taxol in the treatment of breast cancer and like Bissery provides motivation to use an antibiotic in combination with taxol derivative to treat cancer (col. 4, lines 46-51).

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**Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bissery, U.S. Patent 5,908,835 in view of Loshak (XP-002222026: DG Dispatch-ECCO, Sept. 17, 1999).

Claim 17 is drawn to a method for chemotherapeutic treatment of cancer comprising the administration of a chemotherapeutic combination of 4-desacetyl-4-methylcarbonate taxol and doxorubicin and a pharmaceutically acceptable carrier.

Bissery teaches antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic (see abstract). Bissery discloses taxol derivatives and an anthracycline antibiotic combination as the active agents for treating breast, ovarian and lung cancers (see col. 4, lines 46-51). Bissery also discloses in col. 4, lines 37-45, modes of administration, which render the instant methods obvious. The applicant's use of 4-desacetyl-4-methylcarbonate taxol is rendered obvious because the taxol, taxotere and their analogues and 4-desacetyl-4-methylcarbonate taxol have the same core structures (see applicant's figures 2 A, B and C) and the skilled artisan would expect these compounds to have similar properties. Bissery differs from the applicant's invention that Bissery does not provide an explicit example of a composition comprising 4-desacetyl-4-methylcarbonate taxol in combination with doxorubicin, however Bissery

does provide motivation to use an antibiotic in combination with taxol derivative to treat cancer.

Loshak teaches the treatment of breast cancer in women with a combination therapy using taxol with doxorubicin (first para.).

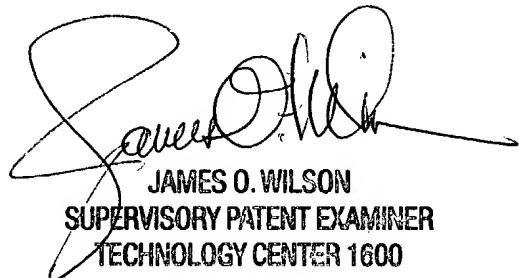
Therefore, one of ordinary skill in this art would have found applicant's method for chemotherapeutic treatment of cancer comprising the administration of a chemotherapeutic combination of 4-desacetyl-4-methylcarbonate taxol and doxorubicin to have been obvious at the time the invention was made having the above references before him because Bissery teaches the antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic. Loshak teaches the use of doxorubicin in combination with taxol in the treatment of breast cancer and like Bissery provides motivation to use an antibiotic in combination with taxol derivative to treat cancer (col. 4, lines 46-51).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571) 272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).  
Art Unit 1623  
April 7, 2004



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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